

College of Pharmacists of Manitoba Lessons from Complaints Trends and Expectations

Learning Objectives

- Examine the role of the College of Pharmacists of Manitoba (College) and the pharmacist in resolving informal concerns and complaints matters
- Distinguish between the separate avenues of resolution: informal concerns and formal complaints
- Examine the possible outcomes of complaint resolution
- Summarize the trends in the types of concerns and contributing factors of complaints matters
- Examine a registrant's duty to report
- Describe the role of Public Representatives in the resolution processes
- Apply best practices for effective and professional communication with patients

Program Agenda

Operations and Processes for Resolution

- Rani Chatterjee-Mehta, Deputy Registrar:
 - Informal concern resolution
- Brent M. Booker, Assistant Registrar Review and Resolution
 - Operations and process of formal complaint resolution

Trends and Expectations for Complaint Resolution

- Pat Trozzo, Chair, Complaints Committee:
 - Examine the role of the the pharmacist in resolving patient safety concerns
 - Identified trends in Complaints matters
- Bharti Kapoor, Public Representative, Complaints Committee:
 - Best practices for effective communication with patients



Rani Chatterjee-Mehta Deputy Registrar Legislation and Resolution

Presenter Disclosure

Rani Chatterjee-Mehta Deputy Registrar, College of Pharmacists of Manitoba

• No conflict of interest to declare

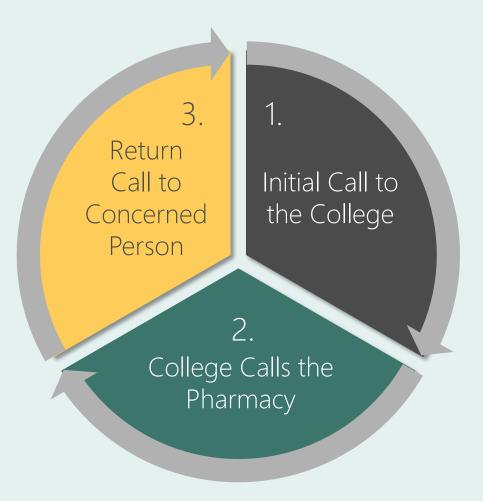
Refresher!

What is the purpose of the College of Pharmacists of Manitoba?

"To protect the health and well-being of the public by ensuring and promoting safe, patient-centred, and progressive pharmacy practice in collaboration with other healthcare providers."

College Mandate

Informal concerns
 Formal (written) complaints
 Two streams for resolution



Initial Call

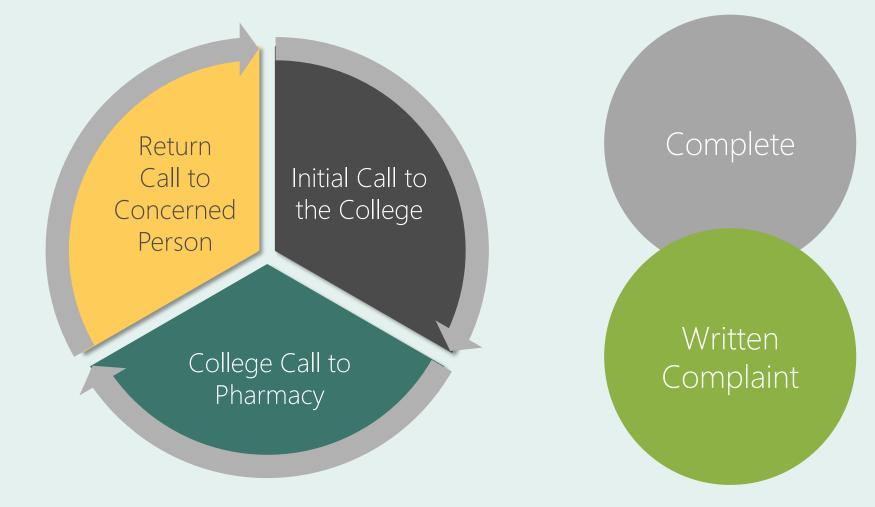
- College gathers information from the concerned person
- College may receive photos or documentation from the concerned person

Call to Pharmacy

Return Call to Concerned Person

Initial Call	 College gathers information from the concerned person College may receive photos or documentation from the concerned person
Call to Pharmacy	 College discusses the incident with the pharmacist or pharmacy manager College may receive information or documentation from the pharmacy
Return Call to Concerned Person	

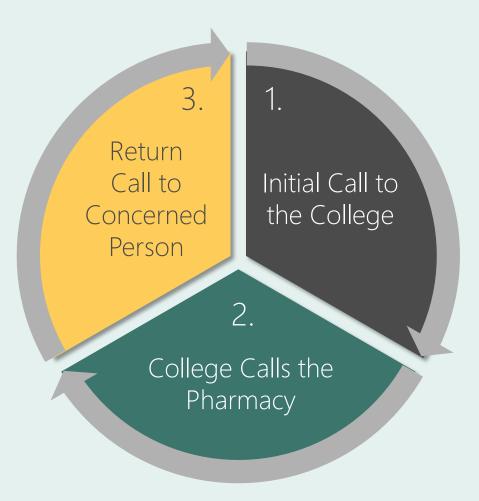
Initial Call	 College gathers information from the concerned person College may receive photos or documentation from the concerned person
Call to Pharmacy	 College discusses the incident with the pharmacist or pharmacy manager College may received information or documentation from the pharmacy
Return Call to Concerned Person	 College will inform concerned person of information gathered from pharmacy College will inform on scope of practice, permitted practices, etc. College will advise of complaint process if concerned person isn't satisfied



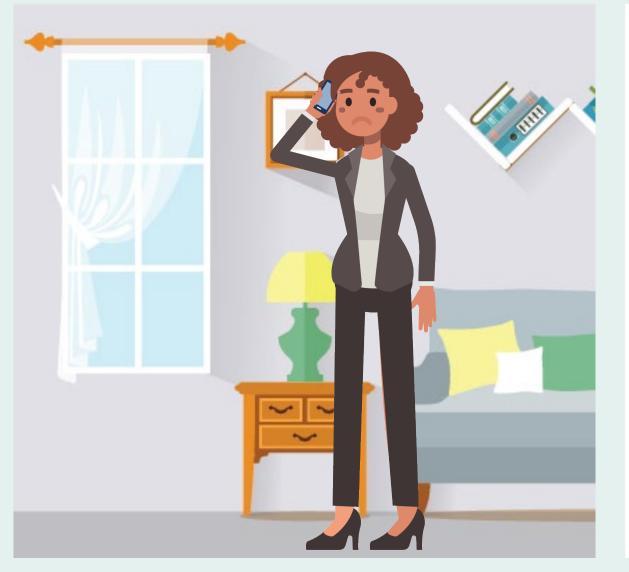
Informal Case Scenario – Patient Transfers

Hi! I'm Jackie

- 36 years old
- Patient for several years
- Patient transfer request
- Delayed despite follow-up



Informal Case Scenario #1





What are your options?

Poll #1: As the transferring pharmacist I can (select all that apply):

- 1. Phone Jackie only to conduct an exit survey so that we can improve our services for other patients
- 2. Complete the transfer and mail Jackie an invoice for the outstanding \$2,500
- 3. Phone Jackie to discuss her outstanding financial balance and let her know that I can't transfer her file until it's paid
- 4. Complete the transfer of Jackie's file
- 5. Phone both Jackie and her new pharmacy to let them know I will complete the transfer as soon as Jackie and I have made the financial arrangements
- 6. Phone Jackie to offer our preferred patient dispensing fee because I know her finances are tight and this might enable her to stay at my pharmacy.

What are your options?

Transfer of Patient Care at the patient's or authorized agent's request

- 2.1 A licenced pharmacist must comply with a patient's request to transfer care to another health professional.
- 2.2 After receipt of a request to transfer care to another licenced pharmacist, the licenced pharmacist must promptly provide the following information to the pharmacy of the patient's choice:
 - 2.2.1 transfer of active prescriptions with remaining refills that can be legally transferred; and
 - 2.2.2 other information that, in the opinion of the transferring licenced pharmacist, may be required to ensure continuity of care.

her finances are tight and this might enable her to stay at my pharmacy

PHIA and Contact after Transfer

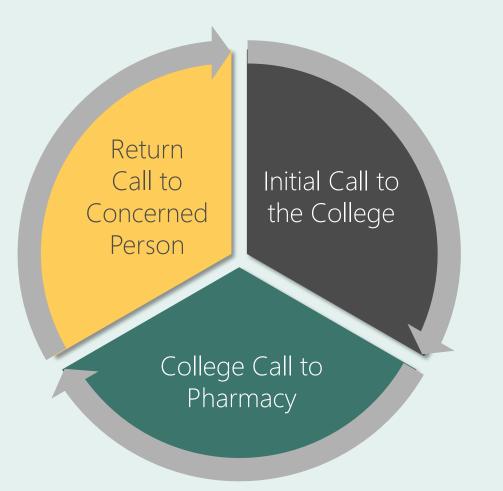
Why can't I ask them what we did wrong after the transfer?

The Personal Health Information Act

21 A trustee may use personal health information only for the <u>purpose for which</u> <u>it was collected or received</u>, and shall not use it for any other purpose, unless...

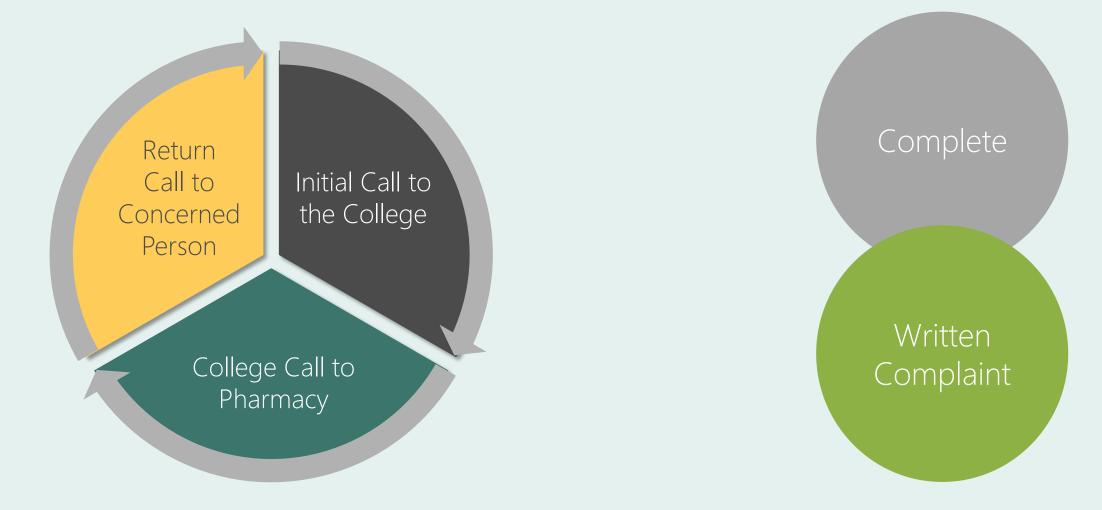
(c.2) the information is <u>demographic information</u> about an individual and is used to collect a debt the individual owes to the trustee, or to the government if the trustee is a department;...

Phase 2 – College Call to Pharmacy



- Inform of your professional obligations
 - Can't delay transfer
 - Advise no exceptions for delay
- Direct to complete transfer

Phase 3 – Return Call to Concerned Person



Trend: Management of Patient Transfers

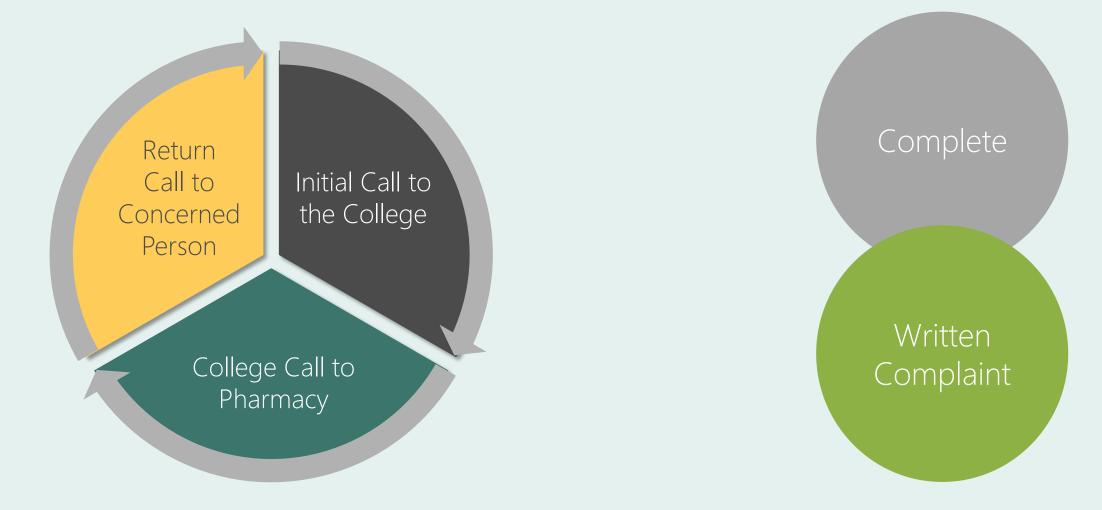
of informal concerns from 2019 related to patient transfers

18%

Obligation

- Don't delay the transfer, action it promptly
- Don't contact the patient
- Provide all info which may assist in continuity of care
- Communicate professionally with the requesting pharmacy staff
- Maintain your documentation

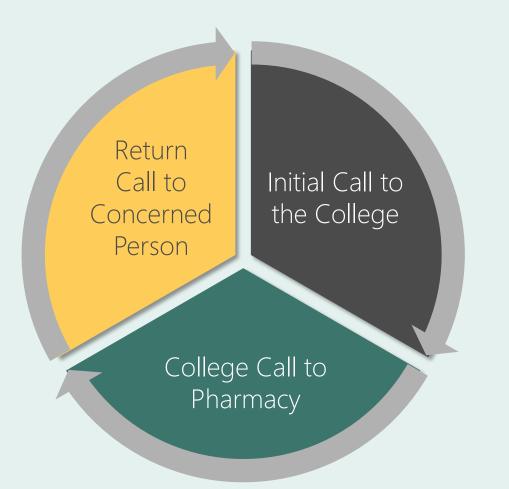
Phase 3 – Return Call to Concerned Person



Recommendations from Complaints

- Avoid personal deductible payment programs
 - <u>Deductible Instalment Payment Program for Pharmacare</u> with Manitoba Hydro and the Manitoba Government
- Maintain clear documentation
 - Payment expectations
 - Payments made
- Maintain professional and respectful interactions

Outcomes of Informal Concerns



• Educational

- Recommendations for improved communication
- Recommended reading or review
- No legislative requirements for documenting informal outcomes



Dr. Brent Booker Assistant Registrar – Review and Resolution Formal Complaints

The Act : s. 29 - 43 The Pharmaceutical Act

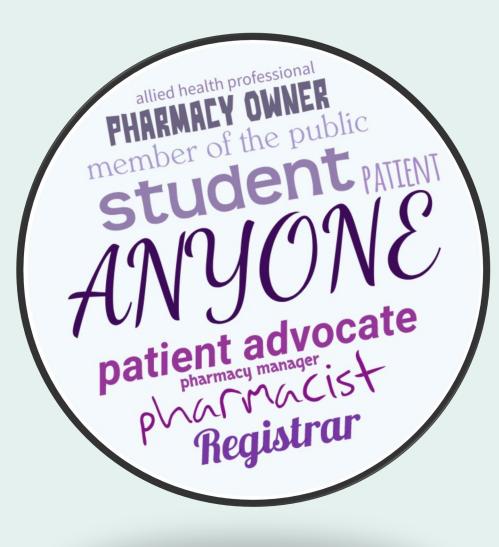
Complaints Resolution Process



Complaints Resolution

Poll #2: Who can submit a complaint?

- a) current pharmacy manager
- b) former pharmacy manager
- c) student (only against their preceptor)
- d) allied health professional
- e) a patient
- f) patient advocate provided they have Power of Attorney
- g) anyone



Complaints Resolution

Poll #3: Who is subject to the complaints process? Select all that apply

- a) member (pharmacist)
- b) former member (pharmacist)
- c) pharmacy owner
- d) former pharmacy owner

- e) pharmacy student
- f) former pharmacy student
- g) pharmacy intern
- h) former pharmacy intern

What Makes a Complaint

- in writing:
 - traditional letter format
 - email
 - fax
- details to be included:
 - Complainants name, address, telephone number and email address
 - name of the pharmacist/pharmacy staff person involved (if known)
 - name and address of the pharmacy
 - specific, detailed account of the events, including dates (if possible)
 - copies of any documentation that support the complaint

Duty to Report

The Act

Duty of members to report

97(1) A member who believes that another member is suffering from a physical or mental condition or disorder of a nature or to an extent that the other member is unfit to continue to practice or that his or her practice or pharmacy operation should be restricted, must inform the registrar of that belief and the reasons for it.

Exemption from liability for disclosure

97(2) A member who discloses information under subsection (1) is not subject to any liability as a result, unless it is established that the disclosure was made maliciously.

Abridged Substance Abuse Toolkit

When does a Concern become a Complaint?

Referral to complaints committee

32 The registrar <u>must</u> refer to the complaints committee

(a) a <u>complaint made under section 31</u>; and

(b) any other matter that the registrar considers appropriate

Complaints against members and others 31(1) Any person, including an inspector, investigator, council member or an officer or staff member of the college, may make a complaint in writing to the registrar about the conduct of a member, student, intern or owner, and the complaint must be dealt with in accordance with this Part.

Registrar's Referral

- Voluntary surrender
- Another healthcare regulator
- Field Operations
- Health Canada
- Manitoba Health
- Adult Inquest Review Committee

Risk Assessment

Interim suspension of a licence:

Interim suspension by <u>registrar</u>

24(1) If the registrar believes that a matter exists relating to a pharmacist's practice or the operation of a pharmacy that presents or is likely to present a serious risk to the public, the registrar may suspend the pharmacist's licence, or the pharmacy licence, pending a review of the matter by the complaints committee.

Suspension of registration or licence pending decision

40(1) Despite anything in this Act, if the <u>complaints</u> <u>committee</u> believes that an investigated person's conduct presents or is likely to present a serious risk to the public, it may direct the registrar to

- a) suspend one or more of the following held by the investigated person:
 - i. certificate of registration,
 - ii. pharmacist licence,
 - iii. pharmacy licence; or

(b) place conditions on the investigated person's practice of pharmacy or pharmacy operation;

pending the outcome of proceedings under this Part.

Composition of the Complaints Committee

- five members, three of whom must be Voting Members (practicing pharmacists) and two of whom must be public representatives
- Chair and Vice-Chair
- quorum: majority of the members committee, including at least one public representative
- practicing pharmacist: hospital and community

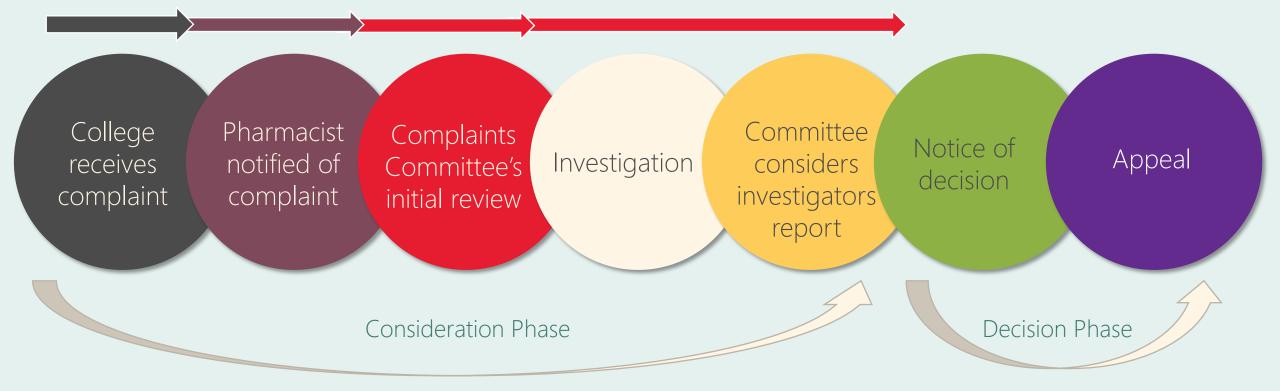
Complaints Resolution Process



Pharmacist notified of complaint

Pharmacist notified of complai<u>nt</u>

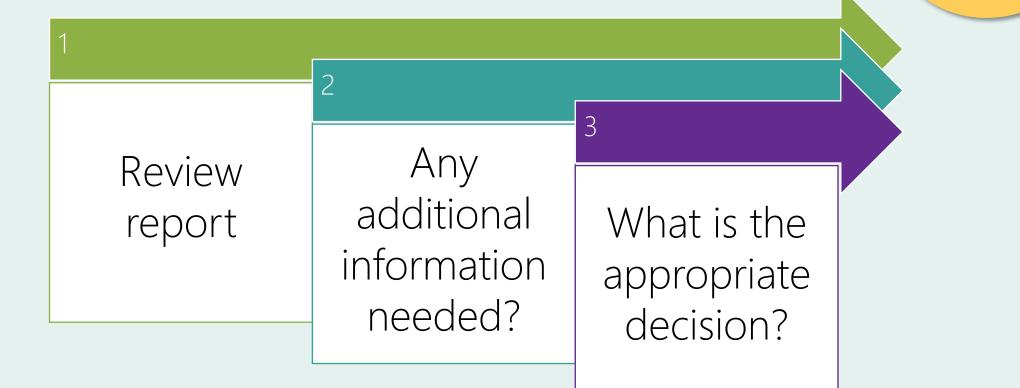
- Written notice by email
- Includes full complaint
- Two weeks to respond
- Response will be shared with complainant
- Demonstrates: self-reflection, accountability, investigation, process or policy changes, apology,



Investigator Assigned	no conflict-of-interest or biasdirection or questions from Committee	Investigation
All parties informed	 possible outcomes: section 34 of <i>The Act</i> investigator contact will follow 	
Interviews	multiple people, multiple timesoften different formats	
Site visits	 may be pre-arranged or unannounced evidence and statement gathering photos and reports from pharmacy software email contact after site visit 	
Report Development	 unbiased report evidence and statements included contravened legislation if allegations are found true 	

Investigation Report Review

Committee considers investigators report



Possible Complaint Outcomes

Committee considers investigators report

- Formal correspondence with recommendations
 - Improved communication
 - Policy or procedural change
 - Assigned change with followup
- Censure the pharmacist
 - Potential for patient risk
 - Learning
 - Growth

- Enter into an **agreement/undertaking** with the pharmacist:
 - Monitoring program
 - Professional development
- Refer to **Discipline Committee**

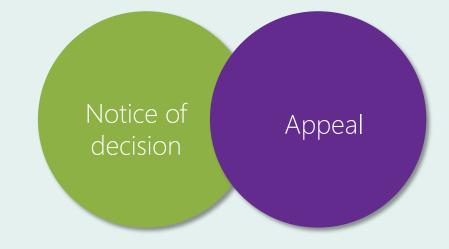
Decision Phase

Notice of Decision

- Written: investigated person and complainant
- Summary of allegations and Committee's concerns
- Recommendations for change and improvement
- Issued by email or registered mail

Appeal

- 30 days from time of receiving the written decision
- Written notice to Registrar





Rani Chatterjee-Mehta Deputy Registrar rchatterjee-mehta@cphm.ca

Brent Booker Assistant Registrar – Review and Resolution bbooker@cphm.ca





Session Break

College of Pharmacists of Manitoba Lessons from Complaints Trends and Expectations



Pat Trozzo Chair Complaints Committee Trends and Expectations

Trends in Formal Complaints

Presenter Disclosure

Pat Trozzo Chair, Complaints Committee College of Pharmacists of Manitoba

• No conflict of interest to declare

Shared Learning – Ask Yourself

How would that situation be handled in our pharmacy?

Would our process have resulted in a more favorable outcome?

Would my regular documentation demonstrate the whole story?"

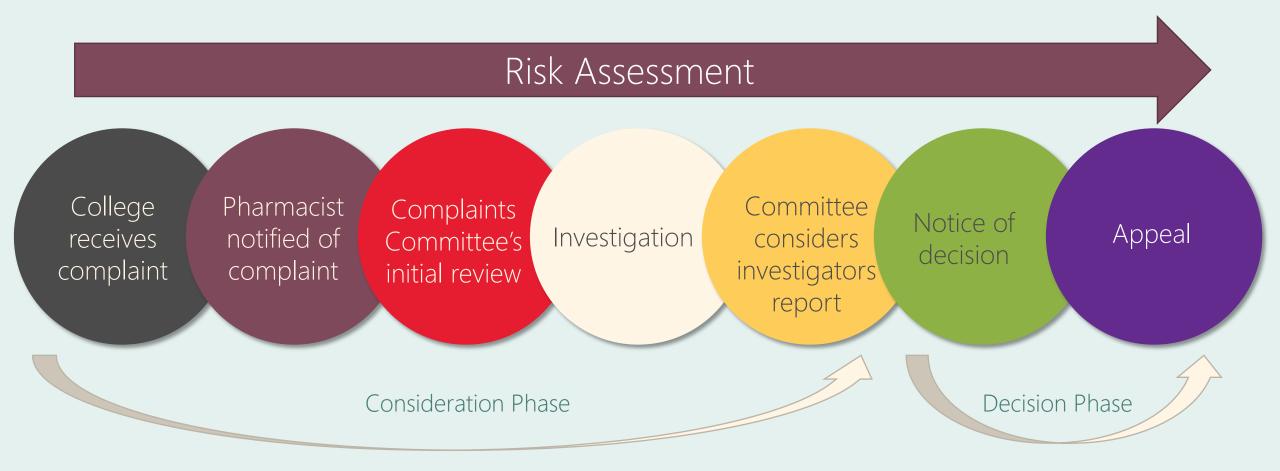
How should we be amending our process to ensure we'd catch it if it happened in our pharmacy tomorrow?

Complaint Case Scenario #1

- August 1:
 - 15 month old patient diagnosed with ear infection, prescribed & dispensed amoxicillin
 - Patient's mother notes packaging states drug name as amoxicillin and clavulanate potassium, previously prescribed amoxicillin for a past ear infection, administers first dose
- August 2:
 - Patient "not taking dose well", first contact to pharmacy to confirm correct drug
 - Pharmacy assures mother that the prescription was for amoxicillin/clavulanate
 - Dosing continued as directed, 10ml twice daily
- August 3:
 - Diarrhea and sever "diaper rash", very sensitive to the touch
 - Dosing continued
- August 4:
 - Contact with pediatrician: advised to immediately stop dosing, prescription was for amoxicillin

Complaint Case Scenario #1

- August 9:
 - Child develops hives, phone consultation with the nurse diphenhydramine hydrochloride and assess next morning
- August 10:
 - diphenhydramine hydrochloride has made no visible impact
 - Low grade fever presents, and hives worsen
 - Hospital for assessments, released and prescribed hydroxyzine
 - No change, pediatrician prescribes ranitidine, loratadine, and epinephrine
 monitor closely
- August 11:
 - Status declines through the night increasing fever and swelling
 - HealthLinks medicate to reduce fever
 - Return to hospital continues to decline
 - Resulted in hospital treatment for 11 days



Risk Assessment

Poll #4: With what we know, could the Committee interim suspend the pharmacist's practicing licence?



Risk Assessment

Interim suspension by registrar

24(1) If the registrar believes that a matter exists relating to a pharmacist's practice or the operation of a pharmacy that presents or is likely to present a serious risk to the public, the registrar may suspend the pharmacist's licence, or the pharmacy licence, pending a review of the matter by the complaints committee.

Suspension of registration or licence pending decision

40(1) Despite anything in this Act, if the complaints committee believes that an investigated person's conduct **presents or is likely to present a serious risk** *to the public*, it may direct the registrar to

- a) suspend one or more of the following held by the investigated person:
 - i. certificate of registration,
 - ii. pharmacist licence,
 - iii. pharmacy licence; or...

Risk Assessment



Complaints Resolution

Poll #5: What information and documentation should the pharmacist include in their response to the complaint? (Select all that apply)

- a) Original prescription
- b) Pharmacy staff schedule
- c) Medication incident report
- d) Copy of the hard copy
- e) Monograph for both meds

- f) Patient file notes
- g) Full P&P manual
- h) Patient counselling log
- i) DPIN history of the patient
- j) Letter to the Committee

Complaints Resolution

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Risk Assessment



Investigation

Investigation

- 1. The patient was prescribed amoxicillin but dispensed amoxicillin/clavulanate
- 2. The prescription was prepared by one pharmacist and checked by another around shift change of a busy day
- 3. The patient's mother did speak to a pharmacy assistant when confirming the dispensed medication was correct and
 - a) the assistant only verified the prescription by viewing what was processed in the system
 - b) The software didn't save a scan of the prescription so the script was not reviewed

Investigation

1.A medication incident report was created and internal investigation by pharmacy manager

2. There was no entry in the counselling log to indicate whether or not counselling took place

Investigation

3.Process is that a pharmacist always hands out medication and opens the bag to confirm the contents – not formalized in P&P

4.Learnings shared: reinforced to support staff that the policy is that a pharmacist must be involved in any inquiries or concerns about a dispensed medication.

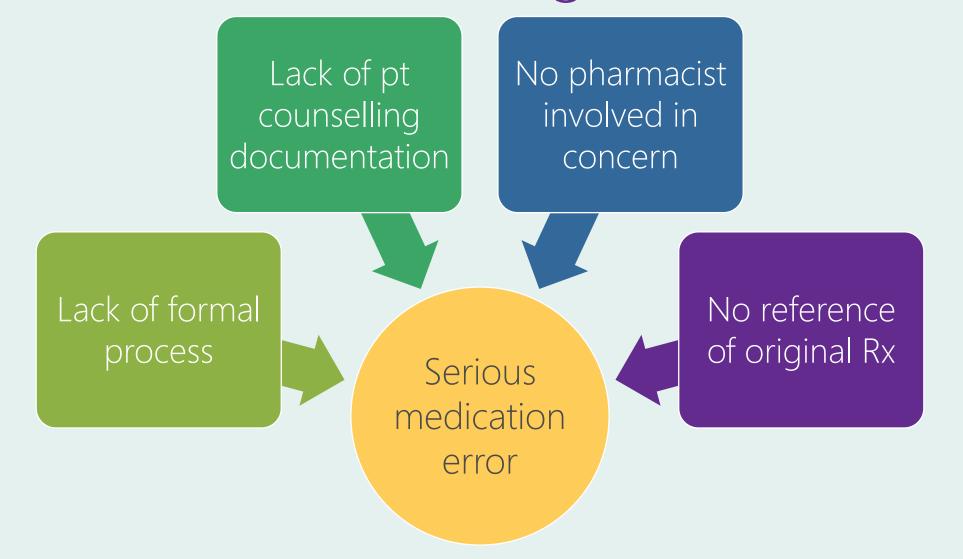
Investigation

Poll #6: What do you think the outcome of this incident would be?

- 1. Formal correspondence with recommendations
 - Improved communication
 - Policy or procedural change
 - Assigned change with followup
- 2. Censure the pharmacistPotential for patient risk
 - Learning
 - Growth

- 3. Enter into an **agreement/undertaking** with the pharmacist:
 - Monitoring program
 - Professional development
- 4. Refer to **Discipline Committee**

Reasons for Considering a Censure





Trends from Case Scenario #1

Formal Policies and Procedures

Policy and Procedure Manual

- Working document
- Specific tasks and responsibilities
- Ensures patient safety

Management of Medication Incidents

- Apology to patient
- Medication incident report
- Internal investigation
- Amended policies and procedures
- Staff communication
- <u>Safety IQ</u>

Patient Counselling

- Required on every prescription
- Patient counselling log
- Document specifics



Complaint Case Scenario #2

- 40 year old female patient
- diagnosed with endometriosis, pelvic congestive syndrome, cystitis, and fibromyalgia
- first prescribed opioids in 2009
- Clonazepam 1 mg 4x/day
- Oxycodone HCL CR 20 mg 2x/day
- Hydromorphone 8 mg 4x/day
- Amitriptyline 100 mg 2x/day
- Baclofen 10 mg at bedtime

- Gabapentin 600 mg 3x/day (08, 12, 16)
- Gabapentin 300 mg at bedtime
- Quetiapine 250 mg at bedtime
- Paroxetine 30 once per day
- Ondansetron 2x/day
- Zopiclone 22.5 mg at bedtime
- Trazodone 250 mg at bedtime
- Weekly dispensing interval

Complaint Case Scenario #2

Tuesday

 patient attended "pharmacy A" and was dispensed the "normal" weekly regimen for the week

Thursday

- attended physician and obtained a new prescription for the week
- Attended "pharmacy B" and dispensed another full week of "normal" regimen

Friday

• patient found deceased – mixed toxicology

"Basically what we are asking is how can a **33 year old**, diagnosed with **treatable medical issues** end up **dying from a drug overdose** 7 years later?

Does the pharmacist not <u>see the potential risk while dispensing</u> these highly addictive medications, as well as the potentially dangerous and or fatal interactions they can, and did cause?

Does the pharmacist notice when the patient is on a <u>prescribed</u> <u>pickup day</u>, if so, why was that prescription <u>filled earlier</u> than the prescribed day?"

Pharmacist Response

Poll #7: What would you include in your response? (Select all that apply)

- a) Original prescriptions
- b) Pharmacy staff schedule
- c) Medication incident report
- d) Copy of the hard copy
- e) Monograph for all meds

- f) Patient file notes
- g) Full P&P manual
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Pharmacy Managers Response

- A new set of Rxs and triplicates was brought into our store ... pharmacy prepared the medications that day and set the patient up on a weekly BP
- Triplicates and the regular Rx have "Please fill all meds today" written on it by the doctor. The regular Rx has "Please fill all meds today then start weekly bubble packs on..."
- Pharmacist: doesn't recall the interaction, pharmacy assistants remember the patient, not any specifics about the interaction
- Pt possibly had explanation on early fill not documented
- obviously a discussion between doctor and pt regarding early fill

"Please fill today"

Poll #8: Is your obligation met in this situation to fill and dispense the prescriptions given the instruction of the prescriber to "Please fill today, and start the bubble packs Tuesday"?



The Pharmacist's Obligation

- Critical care codes
 - "UI" = consulting other sources
 - documented reference in the patient file regarding your actions from critical codes
 - Speak with the prescriber
 - Speak with the patient
- Patient counselling
 - Every prescription
 - Documented in the patient counselling log
 - Notes in the patient profile

Safety Matters: Trends and Learnings from the Medical Examiner

- Clonazepam
- Oxycodone HCL CR
- Hydromorphone
- Amitriptyline
- Baclofen
- Gabapentin
- Quetiapine
- Paroxetine
- Ondansetron
- Zopiclone
- Trazodone

Concerns of the Committee

"Every success story is a tale of constant adaptation, revision, and change" Richard Branson

"Insanity is doing the same thing over and over again... expecting a different result"

Trend: Self-Reflection and Change

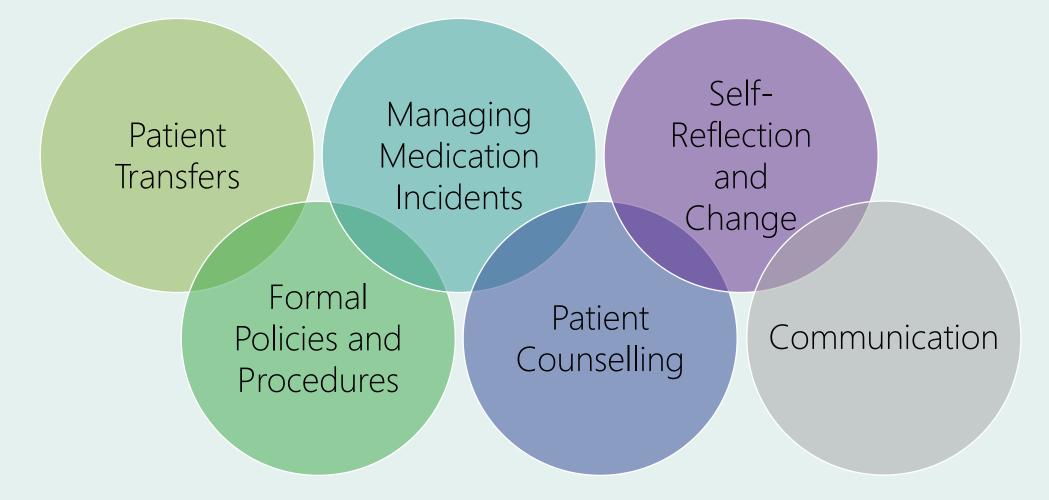
Self-Reflection

- Important for personal and professional growth
- What did I do well?
- What could I have done better?

Change

- What personal practice changes resulted?
- Policy or procedure changes at the pharmacy?
- Shared learnings with all staff

Trend Summary





Bharti Kapoor Public Representative Complaints Committee Communication

Communication

Presenter Disclosure

Bharti Kapoor Public Representative Complaints Committee, College of Pharmacists of Manitoba

• No conflict of interest to declare

Role of Public Representative

- An individual who is not a current or former member, student, intern or owner
- Not an expert in pharmacy, qualifies me
- Perspective of Manitoban patients to help achieve the mandate of the College
- Ensures transparency and accountability to the public

Communication

Poll #9: I believe I am very strong in my verbal communication skills.

- a) True
- b) False

Poll #10: Other people would say I am very strong in my verbal communication skills.

- a) True
- b) False

Communication and Conflict Resolution Tool



College of Pharmacists of Manitoba 200 Tache Avenue, Winnipeg, Manitoba R2H1 IA7 Phone (204) 233-1411 | Fax: (204) 257-3468 E-mail: info@cphm.ca | Website: www.cphm.ca

Communication and Conflict Resolution

Introduction

Communication is central to the work we do pharmacy professionals, whether we coun patients, collaborate with other healthca providers, or consult with colleagues. Strong a effective communication skills result meaningful patient-pharmacy partnerships a effective pharmacy processes that ensu patient safety and positive patient outcomes. On the other hand, poorly manag communication between a pharmacy st

"It goes with the territory. Our job is to actually double-check the accuracy of someone else's prescription. So if we find a problem, we have to deal with it. And if we deal with it, there is the possibility of some kind of **conflict**. No one likes being told they made a mistake." *Pharmacist's experience of conflict*

Pharmacist's experience of confi community pro

A Word from the Complaints Committee

The Complaints Committee found that communication breakdown is frequently a contributing factor in the complaints matters that are brought forward. The breakdown is not limited to an interaction between a pharmacist and patient in complaints matters. The Committee commonly reviews complaints where a communication breakdown has taken place between pharmacy staff (pharmacist or otherwise) from different pharmacies, or between a pharmacy professional and another healthcare professional.

"The Committee commonly reviews complaints where a communication breakdown has taken place between pharmacy staff (pharmacist or otherwise) from different pharmacies, or between a pharmacy professional and another healthcare professional."

Communication – Verbal and Non-Verbal

Poll #11: How much of your message is conveyed verbally?

- a) 16%
 b) 38% ✓
 c) 57%
- d) 62%

Active Listening

- Listening for understanding
 - remove pre-judgment and assumptions
 - focus on their words, tone, context, and nonverbal cues
 - listen to comprehend
- We often listen to respond rather than listen to understand

How many times, have you been so caught up in planning your response in your mind, that you've actually completely missed what your patient is saying in the moment?

How many times, have you been so caught up in planning your response in your mind, that you've actually completely missed what your **patient/spouse/child/parent/boss/employee** is saying in the moment?

Active Listening – Listening for Understanding

- Affirming the patient's feelings empathy
- Asking open-ended and non-judgmental questions *and then* listening to response
- Projecting respect and attention through positive body language
- Anticipating potential conflict, if needed

Communication – Verbal and Non-Verbal

Poll #12: I believe I am skilled at managing an angry patient and deescalating conflict in the pharmacy?

a) True

b) False

Responding to Anger – Do's and Don'ts

- Don't respond with anger
- Do remember the "listen for understanding" strategies
- Do acknowledge the underlying emotion
 - frustration, confusion, or worry

De-Escalating Conflict – AVID Approach

Assume positive qualities about the patient	 They are reasonable, not trying to cause difficulty Outside influences
Validate the unknown	 Ask questions Seek to understand behaviour instead of simply commenting on it
Ignore the unchangeable	 conscious decision to let things go use approach sparingly – may not be appropriate for serious or repeat concern, or action required

Communication

Rani Chatterjee-Mehta

Questions

Dr. Brent M. Booker

Pat Trozzo

Bharti Kapoor









Resources

- The Pharmaceutical Act
- Pharmaceutical Regulation
- <u>Code of Ethics</u> and <u>Explanatory Document</u>
- The Personal Health Information Act
- <u>Practice Direction: Transfer of Patient Care</u>
- Practice Direction: Patient Counselling
- Practice Direction: Medication Incidents and Discrepancies or Near-Miss Events
- Practice Direction: Medication Incidents and near-Miss Events Effective June 1, 2021
- <u>Abridged Substance Abuse Toolkit</u>
- Communication and Conflict Resolution Tool

College of Pharmacists of Manitoba Lessons from Complaints Trends and Expectations

Sy HARMACIS,

Pecte et Suaviter

TOBA